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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/089,835 | 10/28/2002 | Kouichi Ishikawa | 112387 | 5261 |

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Oliff & Berridge
PO Box 19928
Alexandria, VA 22320

03/15/2004

EXAMINER

MALLARI, PATRICIA C

ART UNIT PAPER NUMBER

3736

DATE MAILED: 03/15/2004

11

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/089,835

Applicant(s)

ISHIKAWA ET AL.

Examiner

Patricia C. Mallari

Art Unit

3736

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 October 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 October 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 4.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

Claim Objections

Claim 3 is objected to because of the following informalities: on line 1 of the claim "for testing hepatic" should be replaced with "for testing for".

Appropriate correction is required.

Claim 7 is objected to because of the following informalities: on line 4 of the claim "flow through them" should be replaced with "flow from the breath collecting means through the duct to the breath analyzing section". Appropriate correction is required.

Claim 8 is objected to because of the following informalities: "includes further" online 2 of the claim should be replaced with "further includes".

Appropriate correction is required.

Claim 9 is objected to because of the following informalities:

on line 2 of the claim, "both" should be deleted;

on line 3 of the claim "mask and" should be replaced with "mask,";

on lines 5-6 of the claim "them which is chosen depending a case can be communicate" should be replaced with "the mouthpiece or mask and the breath container communicates";

on lines 6-7 of the claim "is provided" should be replaced with "provided".

Appropriate correction is required.

Claims 14-20 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

The language "used for test for hepatic cirrhosis" in claims 14-20 is merely intended use language which fails to add structure to the breath analyzing apparatus already claimed in claims 3, 4, 7, 9, 10, 11, and 13, thus failing to further limit the parent claims.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 3 recites the limitation "the measurement" on line 5 of the claim. There is insufficient antecedent basis for this limitation in the claim.

Claim 9 recites the limitation "the mouthpiece on lines 2-3 of the claim, "the mask" on line 3 of the claim, and "the communicating opening" on line 4 of the claim. There is insufficient antecedent basis for these limitations in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under

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the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-5, 10, 11, and 14-20 are rejected under 35 U.S.C. 102(e) as being anticipated by Risby et al. Risby discloses an apparatus for testing for hepatic diseases, including cirrhosis (col. 10, lines 33-39) comprising a breath collection section (chamber, col.1, line 64-col. 11, line 4; or gas collection apparatus col. 15, lines 11-13), a breath analyzing section for determining the concentration of at least one of carbon monoxide or carbon dioxide (monitor and computational system; col. 11, lines 40-43; col. 16, lines 17-21), and a data-processing section which analyzes a result obtained by the breath analyzing section (col. 16, lines 21-25; col. 17, lines 1-10). The breath collecting section includes a mouthpiece as a breath collecting means and an outlet port as a breath transfer means (col. 10, line 65-col. 11, line 1; col. 15, lines 15-29). The breath analyzing section may comprise a mass spectrometer (col. 11, lines 36-39). Although Risby fails to specify quantifying isopropanol, the applicants' specification discloses that quantification of isopropanol includes quantifying its decomposition products (p. 6, lines 16-26 of the instant specification), and both carbon monoxide and carbon dioxide are decomposition products of isopropanol (p.2 of "MSDS ALCOHOL 99").

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been

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obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-5, 10, 11, and 14-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 6,248,078 to Risby et al. in view of US Patent No. 5,087,786 to Nubel et al. Risby discloses an apparatus for testing for hepatic diseases, including cirrhosis (col. 10, lines 33-39) comprising a breath collection section (chamber, col. 1, line 64-col. 11, line 4; or gas collection apparatus col. 15, lines 11-13), a breath analyzing section for determining the concentration of at least one volatile organic compound (monitor and computational system; col. 16, lines 17-21), and a data-processing section which analyzes a result obtained by the breath analyzing section (col. 16, lines 21-25; col. 17, lines 1-10). The breath collecting section includes a mouthpiece as a breath collecting means and an outlet port as a breath transfer means (col. 10, line 65-col. 11, line 1; col. 15, lines 15-29). The breath analyzing section may comprise a mass spectrometer (col. 11, lines 36-39). Risby fails to mention specifically isopropanol as a volatile organic compound.

However Nubel teaches that isopropanol is a volatile organic compound (col. 9, line 64-col. 10, line 3). Therefore, it would have been obvious to one of ordinary skill in the art to use isopropanol as the volatile organic compound in the apparatus of Risby et al. since Risby discloses using a volatile organic compound and Nubel teaches that isopropanol is such a volatile organic compound. The description of the apparatus of Risby, as modified, inherently discloses the method of using the apparatus.

Claims 6-9, 12, and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Risby et al. in view of US Patent No. 5,573,005 to Ueda et al. Risby, as modified, is silent as to the details of the breath collection section. However, Ueda discloses a breath collection means comprising an opening for connecting a breath container 12, a duct connecting the breath collecting means to the breath analyzing section (fig. 1) and a valve means 10 which can be switched so that only one of the mouthpiece 8 and the breath container 10 communicates with the breath analyzing section 14 (col. 5, lines 17-30). Breath transfer means also includes pump means (piston of syringe 12 and motor 22), controlled by CPU 40 to send breath to the breath analyzing section (col. 5, lines 47-54). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use the breath collection apparatus of Ueda et al. as that of Risby et al., since Risby discloses using a breath collection apparatus, and Ueda describes an appropriate system.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US Patent No. 6,254,547 to Phillips US Patent No. 6,244,096 to Lewis et al.

US Patent No. 6,221,026 to Phillips US Patent No. 5,996,586 to Phillips

US Patent No. 5,048,31 to Chow US Patent No. 5,961,469 to Roizen et al.

US Patent No. 5,413,775 to Hatfield et al.

US Patent No. 4,083,367 to Portner et al.

"MSDS FOR ISOPROPANOL" to Cornell University

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"Material Safety Data Sheet 2-Propanol" to Rauckman High Voltage Sales, LLC

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia C. Mallari whose telephone number is (703) 605-0422. The examiner can normally be reached on Monday-Friday 10:00 am-6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mary Beth Jones can be reached on (703) 308-3400. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Mary Beth Jones
Acting SPE
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